

§ 5.105 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.

(a) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

(b) The Director and Deputy Directors, Center for Biologics Evaluation and Research, for those drugs listed in § 314.440(b) of this chapter, are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

(c) These officials may not further redelegate these authorities.

§ 5.106 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.

(a) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs with regard to decisions made under section 505(c)(3)(D), (j)(4)(B)(iv), and (j)(4)(D) and section 505A of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 355(c)(3)(D), (j)(4)(B)(ii) and (j)(4)(D) and 355a) concerning the date of submission or the date of effective approval of abbreviated new drug applications including supplements thereto

submitted under section 505(j) of the act (21 U.S.C. 355(j)) and of new drug applications including supplements thereto submitted under section 505(b)(1) (21 U.S.C. 355(b)(1)) of the act and described under section 505(b)(2) of the act (21 U.S.C. 355(b)(2)):

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(b) These officials may not further redelegate this authority.

§ 5.107 Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.

(a) The following officials are authorized to extend or stay an effective date in § 201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

(1) For drugs assigned to their organizations:

(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVR), and Office of Therapeutics Research and Review (OTRR), CBER.

(iii) The Directors and Deputy Directors of the Divisions in OBRR, OVR, and OTRR, CBER.

(2) For drugs assigned to their organizations:

(i) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(b) These officials may not further redelegate this authority.